

510(k) Summary
K100969

Prepared: 9/13/10

Submitter: WMI Enterprises, Inc.
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Chicago, IL 60607
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SEP 20 2010

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Device Name:

Regulation No.: CFR Part 870.5800
Classification: Class II
Panel: 870 Cardiovascular
Classification Name: Compressible Limb Sleeve
Common or usual name: Compressible Limb Sleeve Device
Product Code: JOW
Model #'s: 1000 Series – DVT: D-1000F (foot), D-1000C (calf)
2000 Series – Thermal: T-2000A (ankle), T-2000B (back), T-2000KF (knee full), T-2000KBM (knee, butterfly, medium), T-2000KBS (knee, butterfly, small), T2000S (shoulder), T-2000H (hip)

Indication of Predicate Devices and Statement of Substantial Equivalence:

The 510(k) approval for some of the following listed predicate devices, included approval for electronically controlled pump units and accompanying bladders (wraps, cuffs, sleeves). Our application is for like cuffs only and does not include any electronically controlled pump units. Therefore, our statement of substantial equivalence applies to the cuffs themselves. Our cuffs will be used with the ThermoTek, Inc. NanoTherm and VascuTherm or the Doctors Orders DVTCare units. However, we reserve the right to use the WMI cuffs with other, FDA approved as substantially equivalent electronically controlled pump units in the future.

Based upon safety and performance testing, compliance with voluntary standards, and comparison to the predicate devices in terms of features, functionality, and bench comparison testing, we believe that the WMI intermittent segmental cuffs are substantially equivalent to the wrap portion of the following predicate devices, and do not raise any new questions of safety or effectiveness.

- | | |
|--|---------|
| • ThermoTek, Inc. NanoTherm and VascuTherm | K061866 |
| • Aircast VenaFlow system Disposable Cuffs | K023800 |
| • Doctor's Orders, Inc. DVTcare CA5 | K061125 |
| • Hygia Health Services, Inc. NuTech Foot Wrap | K012650 |
| • Huntleigh Flowtron Excel | K881632 |

Indications for Use

Indications For Use:

- Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema;
- Reduction of edema associated with soft tissue injuries such as ligament sprains, postoperative edema, and burns;
- Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions;
- Decrease the risk of deep venous thrombosis (DVT);
- Aids the blood flow back to the heart;
- Treat and assist healing of cutaneous ulceration (wounds), reduce wound healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.
 - Primary lymphedema (for example congenital/Milroy's Disease)
 - Secondary lymphedema (for example post-mastectomy, chronic edema, post-traumatic edema)
 - Venous disorders (for example venous insufficiency, varicose veins, venous stasis ulcers)
 - Dysfunction of the muscle pump (for example promotion of wound recovery, reduction of edema and lower limb pain following trauma and sports injuries)

Device Description

The cuffs contain interconnected, segmented inflatable chambers constructed of latex-free brushed nylon with polyester foam backing and an internal coating of latex free polymer that creates an airtight seal. The inner lining is elastic, which allows for the inflation. The bladder is constructed of polyvinyl chloride (PVC), RF welded at the seams. The inflation/deflation tubes are also composed of PVC. The hook fasteners are made of polyethylene.

These are pneumatically controlled cuffs, actuated by an electronic pump unit and are designed for single-use. Inflation of the garment is accomplished using air or water and a controller cycle that functions to alternately inflate and deflate the cuffs in a predetermined manner and interval. The garments have only been tested to be used with the ThermoTek, Inc. NanoTherm and VascuTherm pneumatic pumps. Air/water is delivered to the cuff through flexible plastic tubing, inflating it to a specified pressure, to compress the affected anatomical part, thus aiding venous return. Air/water pressure and delivery are monitored by elements within the pump unit. Immediately after the pump element detects that the cuff has achieved the current set pressure, the cuff deflates to ambient pressure, allowing the veins to refill bringing oxygenated blood back to the area. The process essentially simulates muscle contractions in the body area, facilitating appropriate venous flow. The foot cuff simulates ambulation. The cycle continues until the unit is turned off.

Testing

Comparative bench testing was utilized to assess and prove similarity of function between the WMI cuffs and the predicate ThermoTek NanoTherm and VascuTherm wraps. All tests found that functional and operational performance characteristics including compression, pressure control, and timing sequence were substantially equivalent. Safety and operational parameters regarding controller connections were also found to be substantially equivalent. The predicate and WMI cuffs were connected to a ThermoTek

VascuTherm 2 pneumatic compressor pump and cycle tested for 3,000 minutes (50 cycles) at .35 psi (normal usage pressure = .029 psi). The ankle cuffs, as DVT sample, were connected to a ThermoTek VascuTherm 2 pneumatic compressor pump and constant pressure tested for 120 hours (7,200) minutes at 1.9 psi (normal usage pressure = .97 psi). All cuffs demonstrated acceptable cyclic therapy delivery with no differences between cuffs, no migration of cuffs, and no degradation in performance throughout the testing. The testing was successfully completed and resulted in no variance in leakage or performance between the WMI and ThermoTek cuffs. Following life cycle testing, the cuffs were gas pressure tested (burst test). Pressure was introduced and continued until cuffs exhibited leakage or burst. In all cases, the burst point was dramatically higher than normal usage would ever place on the cuffs and the burst points were substantially similar among the cuffs. We believe that all testing supports the substantial equivalence of the cuffs to the predicates.

Summary Comparison Chart

Parameter/WMI	Thermotek K061866	Doctor's Orders K061125	Aircast K023800
Single Patient Use	Yes	Yes	Yes
Non-Sterile (sterilized but not marketing as sterile)	Sterile/Non-Sterile	Sterile/Non-Sterile	Sterile/Non-Sterile
Skin Contact = 200 Denier Nylon Oxford & DuPont Softesse Medical Fabric (non-latex, non-woven)	200 Denier Nylon Oxford & DuPont Softesse Medical Fabric (non-latex, non-woven)	"Soft nylon material"	Latex-free polyester-cotton fabric
Skin Sensitization & Irritation Testing = Yes	Yes	Unknown	Unknown
Cuff/Controller Connectors = Quick-Lock Connectors	Quick-Lock Connectors	Quick-Lock Connectors	Quick-Lock Connectors
Inflation/Deflation Tubing = PVC	Not specified	"Flexible plastic air tubes"	Polyethelene tubing
Intermittent Segmental	Intermittent – both segmental and single chamber	Intermittent single chamber	Intermittent segmental
Energy Source = approved controller pump units that utilize 110 VAC Mains or rechargeable battery	Approved controller pump units that utilize 110 VAC Mains or rechargeable battery	Approved controller pump units that utilize 110 VAC Mains or rechargeable battery	Approved controller pump units that utilize 110 VAC Mains or rechargeable battery



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

SEP 20 2010

WMI Enterprises, Inc.
c/o Ms. Joy Long
DragonSlayer Strategies
1017 W. Washington, 2J
Chicago, IL 60607

Re: K100969
WMI Thermal Cuffs
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: August 9, 2010
Received: August 11, 2010

Dear Ms. Long:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

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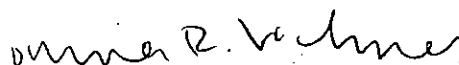
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100969

K100969

Device Name: WMI Thermal Cuffs

SEP 20 2010

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Valente
(Division Sign-Off)
Division of Cardiovascular Devices

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